EXHIBT #1
4 pages

SEP 18 2006

510(K) SUMMARY

This summary of 510(k) safety and effective4ness information is being submitted in accordance with the requirements of SMDA 0990 and 21 CFR § 807.92.

The assigned 510(k) number is: K061532

1. **Submitter's Identification**

Rendoscopy, Inc.
66, Sixth Avenue
Holtsville, NY 11742
Contact: Mira Pattanayak, Regulatory Associate, Tel # 631-586-2086,
Fax # 631-289-5753

Date Summary Prepared:

April 29, 2006

2. **Name of Device:**

Rendoscopy Gentle Colon, revision 2.0

3. **Predicate Device Information:**

G.E. Navigator , 510(k) # K 954355 This system is an add-on to the Advantage Windows Workstation.

4. **Device Description:**

The Gentle Colon contains all of the required software components to provide interactive 3D views from diagnostic CT scan 2D slice cut images of the colon utilizing PC hardware. The views include cross sectional imaging such as axial, sagittal, frontal, oblique, intraluminal, split colon, topogram view, external view of the colon and double contrast visualization. After the CT scan , axial cuts scanned colon image data are transferred to the Rendoscopy work station. The software loads the data from the CT without the need of

manual interaction with the application, enabling the track through the colon including over collapsed parts or over liquid closed lumen.

Surface calculation of the colonic mucosa and splitting of the colon along the track follow automatically. The clip plane is oriented by the maximum curvature of the track, which ensures a free view of the colonic loops or folds.

Rendoscopy's 3D imaging algorithms create surfaces with almost no partial volume effect. Therefore, the 3D images have the highest possible technical contrast resolution, higher than 2D axial cuts.

By splitting the colon the user can get a free view behind the colonic folds, with no distortion. If the gas filled colon tube is interrupted by fluid, or by a collapsed colon part, the user will not run into trouble examining the adjacent colonic part. The Multipath Tracking System will find each path in the 3D dataset without any manual interaction.

This software device provides complete information on cross sectional imaging of any colon location and the information is updated at each step along the track. It is a user friendly, interactive automated Virtual Colonscopy (VC) that uses DICOM data from today's advanced multislice scanners from reputed manufacture. It has been tested and found to work smoothly with different PACS system produced by various manufacturers.

5. Intended Use:

The Rendoscopy Gentle Colon, revision 2.0 is a system for the display and visualization of 3D and 2D medical image data of the colon derived from DICOM compliant CT scans for the purpose of complete colonic mucosa assessment. The user is capable to assure the colonic mucosa image quality through the following provisions built into the software:

- 3D visualization (3D detection, 2D assessment)
- No blind areas behind colonic folds due to splitting colon techniques
- Multipath Tracking System allows path-finding over collapsed or liquid-filled parts of the colon
- The software provides full presentation of cross sectional imaging, such as axial, sagittal, frontal, oblique, intra-luminal, split colon, topogram view, external and unrolled view of the colon and double contrast visualization

It also includes an automatic report creation facility and is intended for use by Radiologists, Clinicians and referring Physicians to process, render, review, archive, print and distribute colon image study reports utilizing PC hardware.

The target population of the Gentle Colon 3D application is the adult patient. It is intended to be used as adjunctive to standard radiology practices for diagnosis, such as the double contrast/barium enema, of the colon.

6. Comparison to Predicate Devices:

The Rendoscopy Gentle Colon System utilizes the same technological characteristics as the predicate device, GE Navigator. Both provide multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. Both provide measurement tools for analysis of the observed structures; allow adjustment to virtual lighting parameters to emphasize details, and provide window/level adjustment of the 2D Views to enhance features.

The predicate device and Gentle Colon both provide external 3D views and endo lunimal 3D views. Gentle Colon system utilizes direct volume rendering for the split colon images. While the endo luminal view is surface extraction performed in a couple of seconds. GE Navigator utilizes surface extraction techniques for all 3D views.

With Gentle Colon, the user may choose between automatic path planning or interactive flight control. The G.E. Navigator also automatically plans a path, but requires the user to build the path in many short segments by pressing a button for each step. In essence, the Gentle Colon system performs the Navigator "auto step and align" function multiple times until the end of the organ is found. Gentle Colon finds all gas filled cylindrical structures automatically, means multi-path segments in the data set are found without manual interaction.

The Gentle Colon system performs a full automated segmentation without manual interaction. The only interaction can be necessary to increase the minimum number of path segments.

G.E. Navigator and Gentle Colon are specifically designed to streamline the typical colon examination. They both provide the ability to load both supine and prone datasets at the same time, even if in loading the dataset in two separate applications. Thy also allow the setting of landmarks (points of interest) and the entering of comments specific to each landmark.

We conclude that the Gentle Colon, is as safe and effective as its predicate device and poses no new questions of safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed

Laboratory testing at unit level and system level were performed in accordance with test scripts/protocol to assure that the Gentle Colon meets all the design specification, performance requirements and intended use of the software device The Gentle Colon passed all final acceptance test/verification.

The Gentle Colon has been developed in a manner consistent with accepted standards for software development. The software was designed, developed, tested and validated according to established procedures and protocols. The product has shown itself to be reliable, easy to use and capable of rendering useful 3D medical images like the predicate device.

8.0 Discussion on Clinical Validation Performed

Clinical validation on thirty patients cases were performed by a radiologist to verify that the system performs as intended. The validation results were compared to the results of predicate device as to determine its quality and effectiveness. The radiologist evaluated both normal anatomy and pathologic findings in well distended and partially collapsed colons with both 2D and 3D reconstructions. The evaluating radiologist found the images are equivalent in all 30 cases using both Gentle Colon and the predicate device.

9.0 Conclusions:

We conclude from the tests and clinical validation that the Gentle Colon is substantially equivalent to its predicate device in its ability to render 3 D images for use in medical diagnostics. The Gentle Colon is as safe and effective as its predicate device, the GE Navigator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 1 8 2006

Ms. Mira Pattanayak
Regulatory Associate
Rendoscopy, Inc.
8 Croydon Court
DIX HILLS NY 11746

Re: K061532
Trade/Device Name: Gentle Colon, Revision 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 1, 2006
Received: September 5, 2006

Dear Ms. Pattanayak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

INDICATIONS FOR USE

510(k) Number (if known) K061532

Device Name: Gentle Colon, revision 2.0

Indications for Use:

Rendoscopy's Gentle Colon, revision 2.0, is a system for the display and visualization of 3D and 2D medical image data of the colon derived from DICOM compliant CT scans for the purpose of complete colonic mucosa assessment. The user is capable to assure the colonic mucosa image quality through the following provisions built into the software:

- 3D visualization (3D detection, 2D assessment)
- No blind areas behind colonic folds due to splitting colon techniques
- Multi-path tracking system allows path finding over collapsed or liquid- filled parts of the colon
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carolyn Y Neuland for N. Braydon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061532